World Council For Health



COVID-19 VACCINE

ADVERSE EVENTS

AROUND THE WORLD

Summary: WCH Covid-19 Vaccine Pharmacovigilance Report

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Approved by: WCH Health and Humanties Committee
June 2022

For the full report visit:
worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report

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About
World Council for Health

The World Council for Health is a non-profit organization for the people that is informed and funded by the people. Our global coalition of health-focused organizations and civil society groups seeks to broaden public health knowledge and sense-making through science and shared wisdom. We are dedicated to safeguarding human rights and free will while empowering people to take control of their health and wellbeing.

Our Vision

We believe in a healthy world where everyone enjoys information transparency, access to proven medicines, and real action in the face of disease – while respecting each individual's personal health decisions, without fear of discrimination or persecution. We believe in a world where we keep our water and air clean, food uncontaminated, and families together.

Our Values

Integrity

Freedom

Transparency

EMPOWERMENT

COMMUNITY

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What is this Document?

This document is a summary of the World Council for Health's comprehensive Covid-19 Vaccine Pharmacovigilance Report prepared in May 2022. **It is for all concerned citizens and clinicians. It summarizes the alarming vaccine adverse events that are being observed in large numbers across several well-established pharmacovigilance databases around the world**. The report aims to establish whether or not there is a safety signal indicating a recall of Covid-19 vaccines.

What is Pharmacovigilance?

Pharmacovigilance is **a pharmaceutical science, also known as drug safety.**
The goal of pharmacovigilance is to:

- **collect, assess, and monitor data about adverse events**
- **prevent adverse events related to pharmaceutical products.**

Most data in pharmacovigilance is gathered through adverse event (AE) reporting, but it is also collected in other ways including population data, studies, and industry reports. Pharmacovigilance databases containing adverse events are an inexpensive and accessible way to detect safety concerns around pharmaceutical products.

How data are gathered:



The data examined in this report is sourced from ADVERSE EVENT reports documented on four well-established pharmacovigilance databases from around the world.

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The Purpose of this Report:

This report aims to determine whether or not there is sufficient data on existing pharmacovigilance databases to indcate a recall of Covid-19 vaccines.

Method:

This report collates data on the following:

- the number of adverse events related to Covid-19 vaccines vs. other commonly administered vaccines
- the types of adverse reactions linked to Covid-19 vaccines
- the rate of adverse events that have been sufficient for product recall in the past

From this data, we determine whether there is sufficient evidence to indicate a recall for Covid-19 vaccines.

The Data We Looked At:

VigiAccess Database
World Health Organization (WHO)

VigiAccess is an initiative of the World Health Organization. It is an international database of reported potential adverse events related to medicinal products.

Vaccine Adverse Event Reporting System
United States CDC and FDA

VAERS is managed by the US Centers for Disease Control and Prevention and Food and Drug Administration. It is an early warning system for safety concerns related to vaccines.

Eudravigilance
European Medicines Agency

Eudravigilance is a database of suspected adverse drug reaction reports. It is used to evaluate, supervise, and monitor safety of medicines in the EU.

UK Yellow Card Scheme
Medicines & Healthcare Products Regulatory Agency

The UK Yellow Card Scheme collects and monitors data on adverse medical incidents or side effects relating to medical products in the UK.

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Why Adverse Event Reporting Matters for Covid-19 Vaccines:

Traditionally, pharmacovigilance data from passive reporting systems are used to detect safety signals for rare adverse events that may have been missed in clinical trials. However, Covid-19 vaccines are unique in that:

Clinical trials are not completed.

Phase 3 and Phase 4 clinical trials for Covid-19 injections are not complete. These phases of trials are designed to establish safety and efficacy and normally last from 10 - 15 years. **These products are being used on billions of people, including children, during their clinical trial phase, and the vast majority are not being monitored.** Their safety and efficacy is UNKNOWN.

6-month Trial Data Showed More Harm in the Vaccinated Group.

In Pfizer's largest clinical trial to date for these products, after 6 months:

- there were 14 deaths in the placebo group and 20 deaths in the vaccine group
- There was a 300% increase in RELATED adverse events in the vaccine group



Covid-19 Products do not Function like Other Vaccines.

Covid-19 products:

- do not prevent someone from contracting, spreading, or becoming ill with SARS-CoV-2
- effectiveness has waned significantly
- are distributed throughout the entire body rather than staying in the arm
- the mRNA, which had never been used in humans prior to 2020, causes the body's cells to produce harmful spike proteins for undetermined amounts of time

Safe Treatments are Available.

Covid-19 can be mitigated and treated with safe, established drugs including antivirals, anticoagulants, and immune therapies.

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Findings:

Total Number of Adverse Events

Summary:

The total number of adverse events related to Covid-19 vaccines on VigiAccess, VAERS, Eudravigilance, and UK Yellow Card Scheme are unprecedented in each database. The magnitude of disparity in the number of adverse events compared to other commonly administered vaccines and therapies is sufficient to indicate an alarming safety signal for these products.

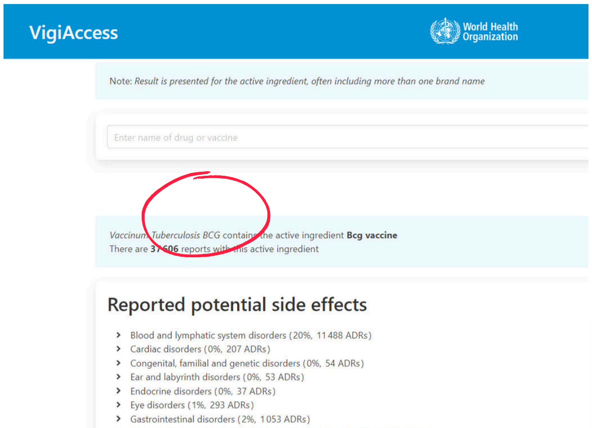
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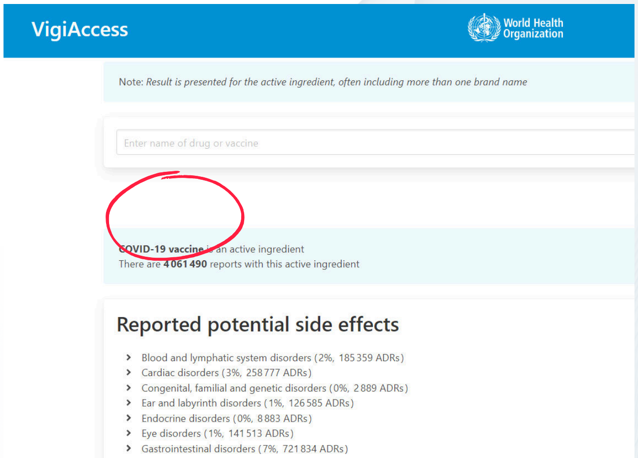
Findings:
Number of Adverse Events

WHO VigiAccess

VigiAccess shows a number of adverse events that is unprecedented on the database for any other pharmaceutical product or vaccine. When we compare it to the Tuberculosis vaccine, for example, which has been administered to more people than any other vaccine, we see the following:

- 37, 000 adverse event reports for Tuberculosis vaccine since 1968
- over 4,000,000 adverse event reports for Covid-19 vaccine since 2020





Total Number Adverse Events on VigiAccess: Common Vaccines

Vaccine	Data Collected Since	Total Number of Adverse Events
Tetanus	1968	15,381
Polio	1968	123,732
Influenza B	1986	90,044
Covid-19	2020	4,000,000

Findings:
Number of Adverse Events (Cont.)

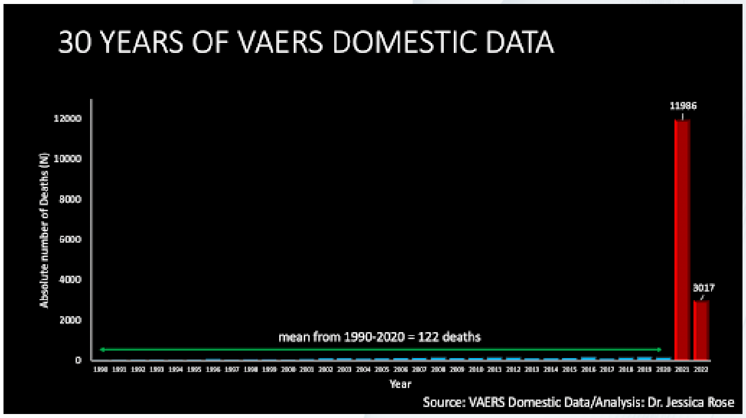
VAERS

Over 50% of total reports in the VAERS database since 1990 are related to the Covid-19 vaccine. There is a 10-fold difference in the number of adverse event reports for the MMR vaccine compared to the Covid-19 vaccine, a 169-fold increase in reported deaths to VAERS after Covid-19 vaccination when compared to the flu vaccine, and a 56-fold increase in adverse event reports on VAERS after Covid-19 vaccination when compared to the flu vaccine.

There are over 1700 reports of adverse events on VAERS for children in children at ages for whom the vaccine was not authorized.

In addition, **VAERS data shows an alarming spike in death reports in 2021 and 2022**. Currently of the over 37 000 deaths reported to VAERS since 1990, 27 968 are related to Covid-19 products.

Average Number of Deaths on VAERS 1990 - 2020:



Risk of Death | VAERS: Flu Vaccine vs. Covid-19 Vaccine:

Vaccine	# of Vaccinations	Number of Deaths	Risk of Death
Flu	167,447,642	33	1 in 5,074,171
Covid-19	173,335,866	5770	1 in 30, 041

Risk of dying from COVID-19 vaccine is 169 times greater than Flu Vaccine

Source: vaersanalysis.info/2022/05/14/vaers-summary-for-covid-19-vaccines-through-5-6-2022/

Findings:
Number of Adverse Events (cont.)

EudraVigilance

EudraVigilance data shows a number of individual case reports that is unprecedented on the database for any other pharmaceutical product or vaccine. When comparing it to the measles vaccine there is a 70-fold increase in the number of events reported to Eudravigilance. There are 48 913 individual EudraVigilance reports linked in some way to the Measles vaccine of the approximate 673 million individuals who have received the vaccine in Europe. It is possible, however, that any amount of these might be attributable to other innoculations contained in the same vaccine. There are 1.8 million individual EudraVigilance reports associated with the Covid-19 vaccines of the approximate 341 million individuals who have received the vaccine.

Total Number Adverse Events on EudraVigilance: Common Vaccines

Vaccine	Approximate Number who have been vaccinated	Total Number of Adverse Events
All Measles Vaccines	673,200,000	48,913
All Polio Vaccines	673,200,000	8982
All Influenza Vaccines	unknown	44,618
Covid-19	341,628,772	1,800,000

Source: https://www.adrreports.eu/

Findings:
Number of Adverse Events (cont.)

Yellow Card

UK Yellow Card

Of the 53 million people who have been vaccinated for Covid-19 in the UK, the Yellow Card Scheme shows over 450,000 yellow card reports related to the Covid-19 vaccines. Comparing this to the data for paracetamol, a medication that has been in widespread general use for several decades, there are only a fraction of the reports (~25 000 since 1968) on the Yellow Card Scheme. The data for other vaccines is not available on the Yellow Card Website.

Total Number Adverse Events on Yellow Card Scheme: Common Medicines vs. Covid-19 Vaccine

Product	Total Number of Adverse Events	Reports since
Paracetamol	25,158	1968
Ibuprofen	16,690	1969
Diphenhydramine (Benadryl)	2165	1964
Covid-19 Vaccine	450,000	2020

Source: https://yellowcard.mhra.gov.uk/idaps

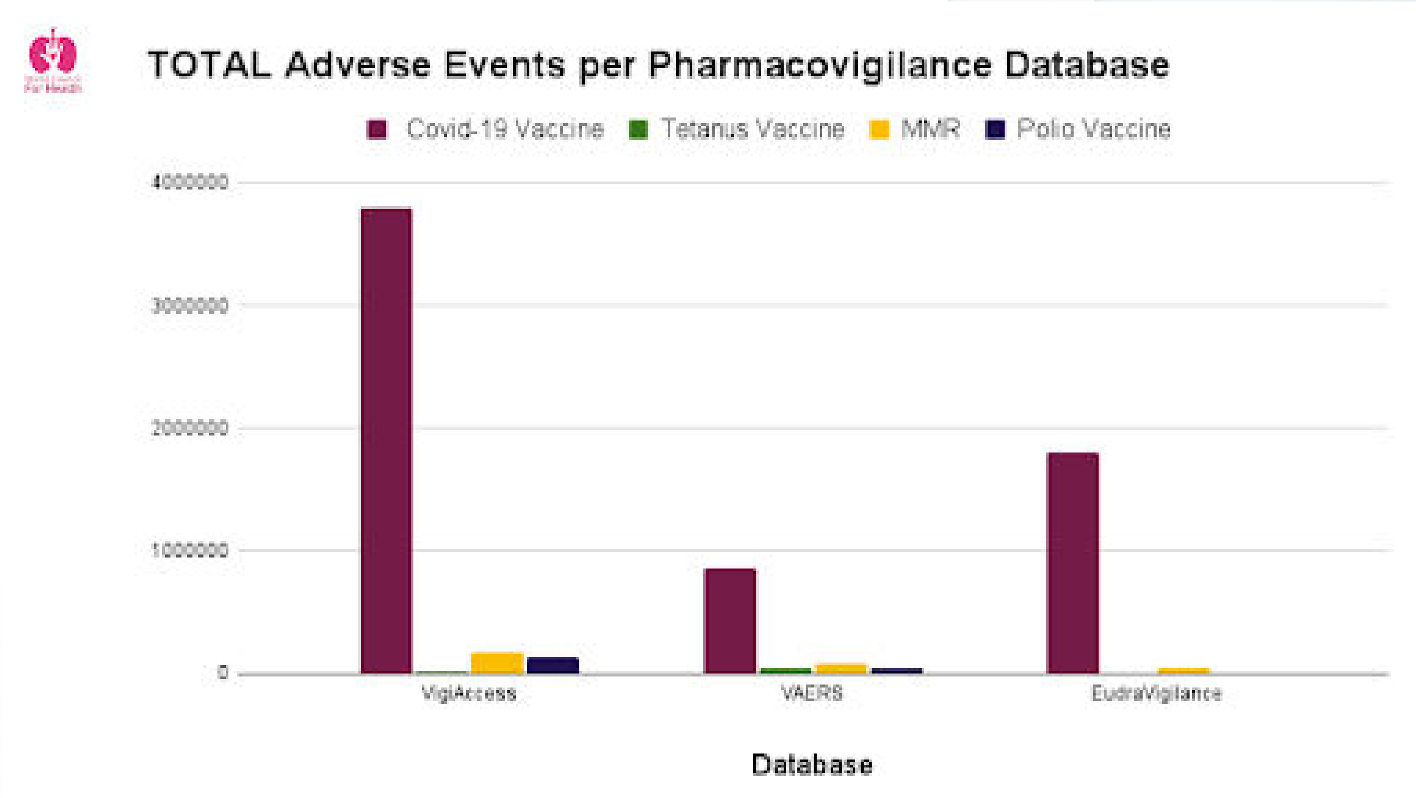
Findings:
Number of Adverse Events (cont.)

All Databases

Across all databases, Covid-19 vaccines show an alarming number of adverse events and death reports when compared to other commonly administered vaccines and medicines

There is a concerning safety signal regarding Covid-19 vaccines detected on all databases examined in this report.

Total Number Adverse Events per Pharmacovigilance Database:



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Findings:

Types of Adverse Events

Summary:

The most common types of adverse events on these databases are:

- Nervous System Disorders
- Musculoskeletal and Connective Tissue Disorders
- Gastrointestinal Disorders
- Anaphylaxis
- Venous Thromboembolism
- Myocarditis/Pericarditis
- Convulsions/Seizures

There are over 50,000 reports of death related to Covid-19 vaccines on these databases.

For the full report visit:
worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report

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Findings:
Types of Adverse Events

All Data

The majority of adverse events reported to all databases are serious in nature, with nervous system disorders being the most commonly reported. There are over 50,000 reported deaths linked to Covid-19 vaccines. Pharmacovigilance databases such as VigiAccess, EudraVigilance, VAERS, and UK Yellow Card Scheme rely on passive reporting from healthcare providers, pharmaceutical companies, and individuals, and **are known to be vastly underreported.**

Most Common AE Reports by Reaction Group

Database	Nervous System Disorders	Musculoskeletal and Connective Tissue Disorders	Gastrointestinal Disorder
VigiAccess	1,500,000	1,000,000	691,000
EudraVigilance	746,000	543,000	344,000
UK Yellow Card	285,000	175,000	135,000

Most Common Reports VAERS: Covid-19 Vaccine

1. Arthritis and Arthralgia/Joint Pain
2. Anaphylaxis
3. Venous Thromboembolism
4. Myocarditis/Pericarditis
5. Stroke and Convulsions/Seizures

Number of Deaths Reported by Database: Covid-19 Vaccine

VigiAccess	VAERS	EudraVigilance	UK Yellow Card
22,000	28,000	800	2100

How Many Adverse Events is Too Many?

Precedent for Drug and Vaccine Recall

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Summary:

The 1967 Swine Flu mass vaccination campaign was halted after a series of adverse event reports including 53 deaths. The Polio Vaccine was recalled in less than 1 year after 10 reported deaths. The Covid-19 vaccine, with over 28 000 associated reports of death on VAERS alone, has not been recalled.

There is sufficient evidence to suggest a recall of Covid-19 vaccines.

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How Many
Adverse Events is Too Many?

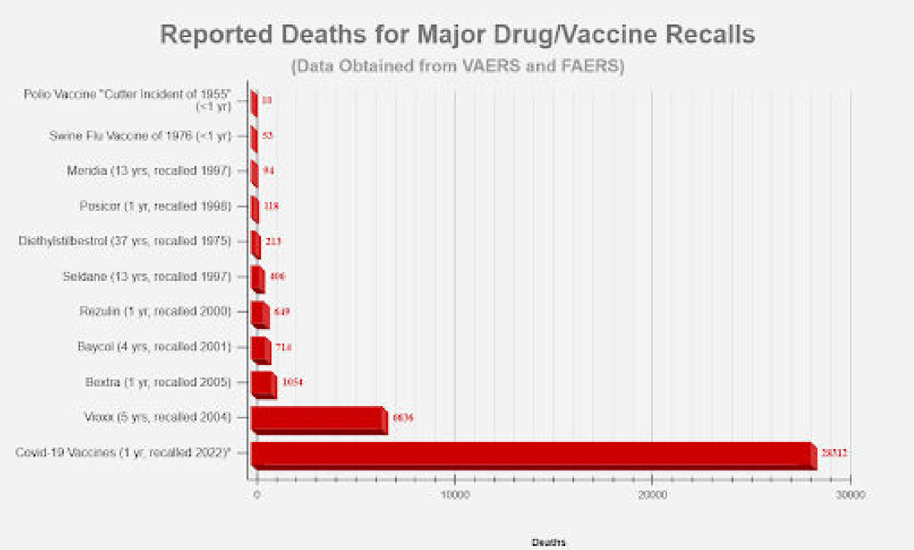
Given that Covid-19 vaccine development was rushed and that they are still in clinical trials, it is imperative to consider how pharmacovigilance data may be used to assess their safety, efficacy, and the case for their continued use. **Precedent from other pharmaceutical products suggests that the data is sufficient to indicate a recall of Covid-19 vaccines.**

The 1976 Swine Flu

In February 1976, an investigation was launched into the mysterious death of an American Private who died during a basic training exercise. CDC tests revealed that Private David Lewis had contracted a strain of swine flu. Subsequently 11 other soldiers tested positive for the virus while hundreds of others tested positive for antibodies. Alarming headlines appeared in newspapers across the country, and, the CDC Director, citing a “strong possibility” of a pandemic, recommended an unprecedented plan of mass vaccination of US citizens.

Though no further evidence emerged that the virus was problematic, the CDC and then President Gerald Ford adopted a ‘better safe than sorry’ approach, and began a mass vaccination campaign for the swine flu. **When reports emerged of suspected adverse reactions, including heart attacks, Guillain-Barre syndrome and 53 reported deaths**, citizens began doubt the safety of the vaccine. Coupled with the fact the pandemic did not materialize as predicted, **the government halted the mass vaccination program** on December 16.

Major Drug and Vaccine Recalls in History:



Source: https://vaersanalysis.info/2022/05/14/vaers-summary-for-covid-19-vaccines-through-5-6-2022/

Signal Detected:
Covid-19 Product Recall Indicated

Unprecedented Numbers of Adverse Events

- All pharmacovigilance databases examined in this report reveal a number of adverse events reports linked to Covid-19 vaccines that are between ten times and 169 times more than what is observed in other commonly administered products
- There are several thousand reports of adverse events in children for whom the Covid-19 product has not been approved

Serious Adverse Events and Death

Data from VigiAccess, VAERS, EudraVigilance, and UK Yellow Card Scheme reveal that the most common reports related to Covid-19 vaccines are:

- Nervous System Disorders
- Musculoskeletal and Connective Tissue Disorders
- Gastrointestinal Disorders
- Anaphylaxis
- Venous Thromboembolism
- Myocarditis/Pericarditis
- Convulsions/Seizures

There are over 50,000 reports of death related to Covid-19 vaccines.

Precedent for Product Recall

- Adverse events are underreported
- Covid-19 products were developed quickly and administered to large populations while still in Phase 3 clinical trials
- Data from VAERS and FAERS reveals that The Polio Vaccine was recalled in less than 1 year after 10 reported deaths, the Swine Flu Vaccine was recalled in less than 1 year after 53 reported deaths. The Covid-19 vaccine, with over 28 000 associated reports of death, has not been recalled after two years

The number and severity of adverse event reports on related to Covid-19 vaccines on these pharmacovigilance databases is sufficient to indicate a recall of Covid-19 products.

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for full report

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